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Feasibility of Magnetic Levator Prosthesis Frame Customization Using Craniofacial Scans and 3-D Printing

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Purpose: To determine the feasibility of a custom frame generation approach for nonsurgical management of severe blepharoptosis with the magnetic levator prosthesis (MLP).

Methods: Participants (n = 8) with severe blepharoptosis (obscuring the visual axis) in one or both eyes who had previously been using a non-custom MLP had a craniofacial scan with a smartphone app to generate a custom MLP frame. A magnetic adhesive was attached to the affected eyelid. The custom MLP frame held a cylindrical magnet near the eyebrow above the affected eyelid, suspending it in the magnetic field while still allowing blinking. The spectacle magnet could be rotated manually, providing adjustable force via angular translation of the magnetic field. Fitting success and comfort were recorded, and interpalpebral fissure (IPF) was measured from video frames after 20 minutes in-office and one-week at-home use. Preference was documented, custom versus non-custom.

Results: Overall, 88% of patients (7/8) were successfully fitted with a median 9/10 comfort (interquartile 7–10) and median ptosis improvement of 2.3 mm (1.3–5.0); $P = 0.01$). Exact binomial testing suggested, with 80% power, that the true population success rate was significantly greater than 45% ($P = 0.05$). Five participants took the custom MLP home for one week, with only one case of mild conjunctival redness which resolved without treatment. Highest to lowest force modulation resulted in a marginally significant median IPF adjustment of 1.5 mm (0.8 to 2.7; $P = 0.06$). All preferred the custom frame.

Conclusions: The three-dimensional custom MLP frame generation approach using a smartphone app–based craniofacial scan is a feasible approach for clinical deployment of the MLP.

Translational Relevance: First demonstration of customized frame generation for the MLP.

Introduction

Blepharoptosis, defined as incomplete opening of the upper eyelid, occurs because of abnormalities in the function or structure of the levator palpebrae superioris muscle, injury to or dysfunction of the superior division of the third cranial nerve, or structural abnormalities.[1] Causes include congenital abnormalities, stroke, traumatic brain injury, tumors of the brain or face, viral illnesses, diabetes, autoimmune neuromuscular disorders such as myasthenia gravis, and general aging mechanisms.[1] The prevalence of blepharoptosis within the United States general population is unknown; however, in Korea and the United Kingdom general population, it has been reported to be ~11%,[2,3] suggesting that 30 million people in the United States may have the disorder.

The most common method currently used to correct ptosis involves surgical tightening of the levator muscle (external levator aponeurosis advancement procedures) or, in more severe cases, a frontalis sling.[1] Although

these procedures are a mainstay of treatment, in our experience they have disadvantages in that they do not always restore normal blink function, and overcorrection may result in exposure keratitis. In severe cases of ptosis, a conservative approach is needed leaving the ptosis undercorrected, and so even surgical candidates may benefit from magnetic correction.

Substantially less attention has been given to nonsurgical approaches for ptosis, which has led to a lack of effective options during the early recovery period from neurological causes such as stroke or severe head trauma, in cases with daily variability in the ptosis such as myasthenia gravis, or in cases where surgery is contraindicated. Very recently, a nonsurgical pharmacological approach was approved by the United States Food and Drug Administration for age-related ptosis, oxymetazoline drops, which activate Muller's muscle and were found to provide about 1 mm of improvement in lid position.[4] Although a good option for mild cases, this amount of ptosis improvement is not sufficient to address severe neurogenic cases of ptosis. Oversized scleral contact lenses that mechanically elevate the lid have also been reported in case studies and series and represent an innovative approach for patients who are already wearing a scleral lens for corneal disease.[5–7] Other commercially available temporary or nonsurgical treatments are ineffective and even contraindicated for many target populations. These include taping the lid(s) open and propping the lid open with a wire on the glasses (ptosis crutch).[8] Both options mechanically elevate the lid and do not allow full and natural eye closure, creating risk for corneal desiccation and epithelial defects. The crutch, which consists of a wire attached to the glasses as first described by Goldzieher in 1890,[9] was quickly faulted by Dr. A. Meyer in 1893, an ophthalmologist himself having ptosis, for its inability to allow a "wink."[10] A solution using a spring was suggested by Meyer, but, unlike the basic crutch, springs have not achieved sustained clinical use. We also have concerns that the crutch could cause injury with a fall or other blunt trauma or an abrasion during the necessary frequent adjustment, and at minimum is likely to be a constant mechanical irritant. It has recently been proposed to custom design and print crutches,[11,12] but customization does not address the main issues of eye closure and mechanical irritation. Traditional wire crutches are in fact customizable already by bending the wire. To address shortcomings of existing approaches, we developed a novel nonsurgical magnetic eyewear device referred to as the magnetic levator prosthesis (MLP).[13–17] The force to lift the lid is produced by a static neodymium magnet embedded in a glasses frame and a polymer-embedded polydimethylsiloxane (PDMS) micro-magnet array fitted externally to the upper lid with Tegaderm IV securement film, simply described as "magnetic tape." Because these are static magnets, no power source is required, making them quite feasible for clinical use. Ideally, the magnetic lid-attached element and spectacle frame magnet casing never come into direct contact. Instead, the eyelid should be elevated by the magnetic force and then suspended in the open position within the magnetic field without touching the frame casing, with the force being low enough to be easily overcome for natural blinking. This ideal response has been achieved in some cases published previously (and in some of the cases shown later in this article, Fig. 1D, Fig. 6, S2, S6, S9). In a clinical study within an inpatient rehabilitation facility where the MLP was used for participants with severe paralytic ptosis, the magnetic array remained affixed to the eyelid skin for a mean of 6 ± 4 days with good reported comfort when used for two hours per day during rehabilitation therapies.[17] Weight of the spectacle magnet and difficulty with self-application were the most commonly reported challenges. Depending on the structure of the face and the available frame, a portion of the sample experienced contact between lid and spectacle magnet casing, creating some difficultly with closure because of high forces (Fig. 1A). We attempted to address this during that study by putting barrier material (an adhesive felt) around the outside of the spectacle magnet (Fig. 1B). Although this reduced the force, contact between eyelid and felt was a mechanical irritant, albeit better than the comparison crutch, and it limited the amount of opening, blocked part of the visual field, and was unsightly (Fig. 1B). A better solution would be an improved frame fit, if possible, allowing this ideal suspension non-contact fitting (Fig. 1D). Additionally, in that study, fitting of participants with low bridge anatomy, common in most Asian and many Black individuals, was not very successful in our sample because the traditional frames slid down with the added weight of the spectacle magnet. However, when the frame was held up higher in place, response was good (Fig. 1C), suggesting that if frame fitting could be addressed, the approach would be effective. Because of the nonlinear magnetic force-distance response characteristic of magnetic fields, a well-fitting frame is critical to the success of the MLP.

To address the challenges in frame fitting, the feasibility of using custom frame design and three-dimensional (3-D) printing technology was implemented and evaluated. In addition, a novel adjustable force feature that used angular translation of the static magnet via a small lineal dial on the spectacle magnetic housing was implemented, which is described in a patent application[18] and in human demonstration (Mahil A, et al. OVS 2019; 96:E-abstract 195441). A custom frame version of the MLP was developed using existing commercially available techniques

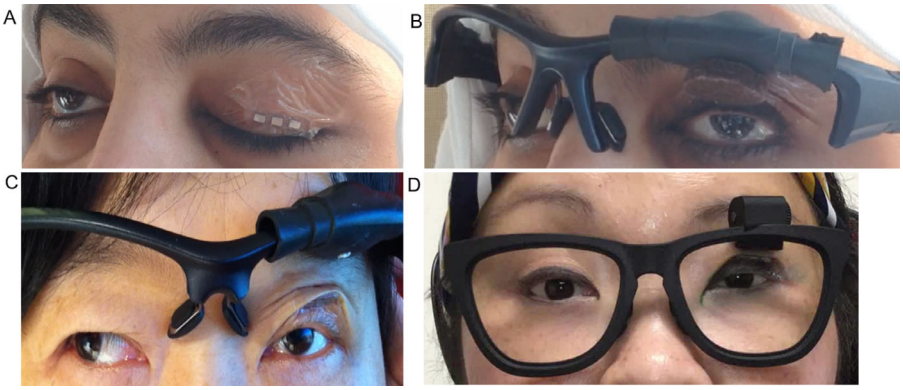

Figure 1. (A) Participant with severe paralytic ptosis from the prior inpatient pilot study[17] wearing an early version of the MLP lid device attached noninvasively with hydrocolloid film. Notice that while the device is effective, the eyelid magnet and spectacle magnet case are in direct contact, which is not ideal. (B) Same participant wearing an early non-custom prototype MLP frame. The spectacle magnet, which is mounted above the left eye onto the sports frame using heat shrink tubing, cannot be easily interchanged, and the nosepads had limited ability for adjustment. (C) A participant of Asian descent and low bridge anatomy from a prior study[17] could not be fitted with this early frame prototype. The frame was being held in place by the clinician to obtain eye opening. (D) Example of a custom 3-D printed MLP frame with adjustable force magnetic housing from the present study, illustrating successful fit in a different participant with low bridge anatomy.

available for custom sunglasses production (Skelmet, Inc, Boston MA, USA), which involved 3-D craniofacial scans performed with a smartphone app. The available custom sunglass frame design was then modified to incorporate a built-in adjustable force magnet housing.

In this phase I equivalent proof-of-concept study, the aims were (1) to prototype the built-in component system and (2) to demonstrate the clinical feasibility in participants with severe blepharoptosis. The primary hypothesis was that there would be statistically greater than 50% fitting success rate with the custom system. This 50% benchmark was set by consultation with clinical low vision rehabilitation optometry specialists, who indicated this would be the minimum success rate that would make clinical implementation feasible. This success rate is similar to spectacle-mounted low vision aids such as bioptic telescopes. A second benchmark was a greater than 1 mm change in interpalpebral fissure across the adjustable force range in statistically greater than 50% of participants, indicating that this feature was likely to be useful in at least half of patients.

Material and Methods

Magnetic materials and parameters where selected based on prior clinical testing.[15,17] To summarize, spectacle magnets were cylindrical 9.53 mm in diameter by 12.7 mm in length diametrically magnetized nickel-coated NdFeB-52 (neodymium, iron, boron) static magnets with a magnetic flux density of 0.58 Tesla (T) (5800 Gauss), on the magnet surface at the pole (SM Magnetic, Pelham, AL, USA). The lid attached devices consisted of 2 mm high × 3 mm wide × 1mm thick cubes of the same material (0.20T each, on the width surface [2000 Gauss]) embedded in PDMS and attached to the lid with IV3000 securement film (Smith and Nephew, Watford, UK). Lid devices with two or three cube magnets polarized through height or through thickness were available to the study clinical technicians for fitting and were selected for fitting based on their clinical judgment. The 3-D finite element analysis simulation with multi-physics software (Comsol, Burlington MA, USA) suggested a 12 gram-force(gF) variation from lowest (poles orthogonal) to highest (poles aligned) force setting for the magnets used in this study (modeled for a 3-magnet lid device), when separated by 10 mm (a clinically feasible and typical distance). Details on the force modeling along with empirical verification is the topic of a separate manuscript planned for publication, and so is not reported in detail here. For custom frame prototyping, a design, inspect, test, and refine method was used via meetings between study engineers and clinicians. Two prototypes with multiple iterations were required before arriving at study end version.

Participants

The study was conducted in accordance with the tenets of the Declaration of Helsinki. Informed consent was obtained from the participants after explanation of the nature and possible consequences of the study for a protocol approved by the institutional review board at Massachusetts Eye and Ear. The Magnetic Levator Prosthesis was judged by the human subjects committee, institutional review board, and affiliated consultants, to be a non-significant risk device; therefore, a United States Food and Drug

Administration Investigational Device Exemption was not required. The device is expected to be Class I, meaning it will not require pre-market notification to the Food and Drug Administration. The trial was registered through the United States Clinical Trial registration site, clinicaltrials.gov, prior to enrollment of the first participant (identifier NCT03818204).

Inclusion criteria included presence of blepharoptosis for at least one eye that obscured the visual axis in the resting position (without frontalis drive, lifting with forehead muscles), moderate cognitive function or better defined as greater than or equal to 18 out of 30 on a pre-screening of the Mini-Mental State Exam, and age 18 to 88. Exclusion criteria included absence of severe blepharoptosis (must occlude visual axis), presence of a corneal ulcer, corneal hypoesthesia, absent or incomplete orbicularis oculi function, age less than 18 or greater than 88, severe cognitive impairment defined as Mini-Mental Status Exam score <18, behaviors consistent with delirium (combinations of disorientation, hallucinations, delusions, or incoherent speech), or lethargy. These individuals were excluded because participation required competent self-care, reliable responses, and cooperation during fitting of the devices.

Participant Visits and Study Procedures

Craniofacial Scan

A 3-D head and face scanning was performed with a smartphone-stereo camera attachment (Structure Sensor, Occipital Inc., Boulder, CO, USA) with iPhone 8 (Apple, Cupertino, CA, USA) and an app produced by Skelmet Inc., which guided the user through the data acquisition (Fig. 4). The clinician placed a round sticker on the participant's eyebrow directly above the pupil, to mark the desired position (in the scan) of the spectacle magnet housing. The participant wore a hair cap to reveal the ears, and the stereo camera was moved slowly around and above the head while the participant was instructed to hold absolutely still, requiring less than one minute. The scan was promptly sent to the frame manufacturer (Skelmet Inc.) whom reviewed the scans immediately and requested repeat scan if quality was not acceptable. Participants were scheduled to return once their custom frame was ready (approximately two weeks).

Custom Frame Fitting Visit

Baseline measurements were taken for visual acuity and slit lamp with sodium fluorescein, and National Eye Institute ocular surface staining scale was completed. Video recordings were made with an iPod Touch (Apple) at 30 Hertz for 15 seconds, while comfort was monitored with a 10-point scale (1 = poor comfort to 10 = best comfort). Next the eyelid was prepared using a lid scrub (OCuSOFT, Richmond TX, USA), and an MLP lid device was applied with the first magnet centered over the pupil, approximately 2 mm from the eyelid margin of the affected upper lid (Fig. 2). Next, the custom MLP frame was donned, and interchangeable nose pads were used to make minor adjustments to the fit. The lid magnets were embedded in PDMS, and the spectacle magnet was encased in the frame material, greatly limiting the potential for an adverse event from strong spectacle-to-eyelid magnet adhesion. Additionally, there were "buffers" of three different thicknesses (1, 2, and 3 mm) made of the same material as the frame that could be clipped over the spectacle magnet casing, at the study clinician's discretion, if they noticed adhesion causing discomfort or poor blink. Buffers were needed in all participants except 2 and 6 (Fig. 6). The adjustable force dial, which could be used to manually rotate the spectacle magnet within the frame and thereby translate the magnetic field to modulate force on the lid device, was set to either its highest or lowest force setting, counterbalanced. The highest force occurred where the north pole of the spectacle magnet was aligned with the south pole of the lid magnets, calculated at 12 gF for 10 mm separation. The lowest force setting occurred when the poles were at 90° to one another, 0 gF for 10 mm separation. After 15 seconds of recording, the adjustable force setting was switched and video

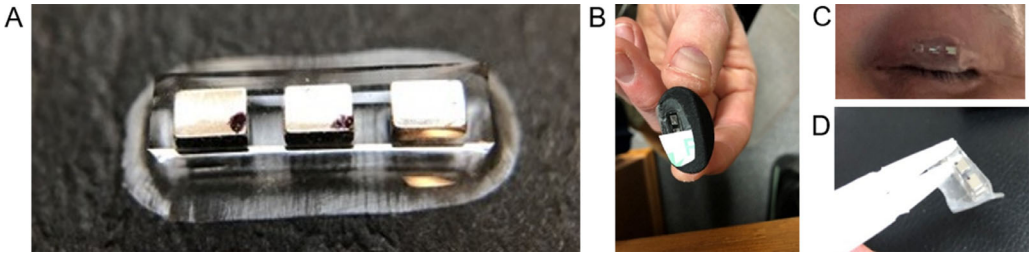

Figure 2. (A) Magnified view of the MLP eyelid device. (B, C) Application process for the eyelid device. (D) The device is easily removed with contact lens tweezers. Without removal, the device typically remains adhered for multiple days.

Table. Participant Characteristics

Participant	Age (y)	Gender	Ptosis Side	Baseline Resting IPF* (mm)	Cause
1†	28	M	Right	3.1 ± 0.05	CN III palsy, TBI
2	18	F	Left	4.9 ± 0.13	CN III palsy, brain abscess
3	78	F	Right	0.0	Stroke, nuclear CN III
4†	23	M	Right	0.0	Trauma
5	41	F	Left	6.1 ± 0.13	CN III palsy, tumor
6	60	M	Both	3.4 ± 0.19 3.8 ± 0.20	OPMD
7	56	M	Both	5.3 ± 0.05 4.5 ± 0.05	OPMD
8	28	F	Both	7.2 ± 0.04 8.5 ± 0.11	CPEO
9	43	M	Left	4.6 ± 0.07	Congenital
10	71	F	Left	0.5 ± 0.03	Sphenoid wing meningioma

CN III, Cranial Nerve III; TBI, traumatic brain injury; OPMD, oculopharyngeal muscular dystrophy; CPEO, chronic progressive external ophthalmoplegia; IPF, inter-palpebral fissure.

*Defined as the mean baseline IPF during resting open. 0 mm = complete ptosis.

†Participants 1 and 4 were enrolled but exited the study due to recovery (1) and facial nerve – orbicularis weakness discovered after enrollment (4).

recorded for another 15 seconds. At this point, if comfort was five out of ten or better and the clinical staff determined it was safe to proceed, the participant was given the option to participate in a 20-minute trial. Before the trial, the clinician adjusted the force dial to one of the available force settings, attempting to achieve the best performance. The 20-minute trial was performed with this "best" fit. After the 20-minute trial, visual acuity, slit lamp with sodium fluorescein scale, and video recordings with comfort scale were repeated.

Primary Outcome

After the 20-minute trial it was determined whether the fitting success criteria were met, representing the primary outcome measure of the study. If so, the patient was given the choice to do a one-week at-home trial. If the device needed modifications, additional visits were conducted, repeating the above procedures. Once the device was dispensed for home use the patient returned one week later where visual acuity, slit lamp with sodium fluorescein, and video recordings with comfort scale were repeated. At that point the study was complete.

Safety Cutoffs

Predefined criteria for an adverse events included visual acuity decrease more than two lines, worsening of corneal staining rating of more than 1.5 points or conjunctival surface rating more than two points, and comfort rating lower than five of 10. Serious adverse events that would have required immediate dismissal from the study included (1) development of a corneal epithelial defect with or without infiltrate or (2) broken skin on the eyelid (skin decompensation).

Ten participants were planned for enrollment. Ten were enrolled, and eight completed the study, shown in the Table. Participant 1 exited before being fitted with the custom MLP because of recovery of the traumatic third cranial nerve palsy, and participant 4 was removed from the study after consent because of discovery of facial nerve–orbicularis weakness due to a traumatic seventh cranial nerve palsy on the same side as the ptosis.

Non-Custom MLP Frame

All participants were part of another study which had provided them with a non-custom version of the MLP frame, which allowed for preference to be documented. The details of this non-custom frame design and study procedures are the topic of another study currently in preparation. To summarize, a 3-D–printed spectacle magnetic housing clip with a similar adjustable force dial was attached to a standard eye wear frame, and blinking was measured across

different angular rotations of the spectacle magnet. Testing for this non-custom device study was typically done, in part, at the same visit as the craniofacial scan.

Data Collection and Processing

Counts of adverse events, binary preference data, and choice outcomes were tabulated. The median interpalpebral fissure measured over the 15 seconds of recording was calculated for each participant condition, and then median and twenty-fifth to seventy-fifth interquartile range calculated. Medians (and not means) are reported due to the non-normal distribution and small sample size. Medians and interquartile ranges were calculated for comfort ratings.

Image Processing and Measurement of Interpalpebral Fissure

Video files were decomposed to image stacks and imported into the National Eye Institute's open-source image processing software, Image J (NEI, Bethesda, MD, USA). Pixel to real space calibration was done using the population average 11.67 mm horizontal visible iris diameter, previously demonstrated as a reliable method for calibration.[17]

Data Analyses and Statistical Methods

The primary outcome was an exact binomial test of one proportion to determine if the observed proportion met the expected benchmark (50% success). All statistical analyses were performed with STATA/IC 16.1 (College Station, TX, USA) and are reported when $\alpha \leq .01$ (statistical significance).

Results

Prototyping Results

Two different prototypes were produced and evaluated, which was conducted in the laboratories of the authors before the described attempts to implement the approach into the custom Skelmet Inc. sunglasses frame. This process is described in detail in a manuscript in production currently, and is summarized here. The first prototype required drilling of the spectacle magnet in order to affix the magnet into the housing cavity, and a lineal dial was glued to the front of the magnet (Figs. 3A, 3B). This prototype was not durable, and so failed inspection and was not tested with participants. Drilling of the magnet was expensive and affected integrity. To correct these issues, a complete redesign resulted in a second prototype which implemented a sleeve to seat the cylindrical spectacle magnet (Figs. 3C–F), eliminating the need for drilling.

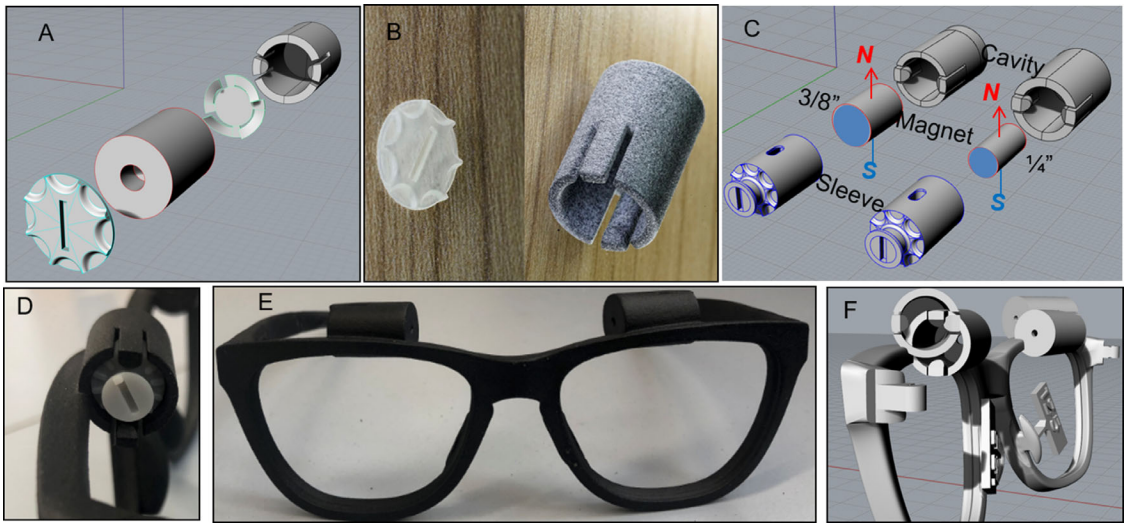

Figure 3. Prototyping conducted of the non custom (A–C) and custom (D–F) MLP frame. (A) Initial design with lineal dial required drilling of the cylindrical magnet, which was costly and affected magnet integrity. (B) First 3-D–printed prototype from (A). (C) In a re-design, a sleeve was used to hold the magnet, which was glued in place and was then inserted into the cavity. A spring (not shown) kept tension on the dial apparatus. The magnet was rotated by pushing in and turning. (D, E) A 3-D–printed prototype of (B) showing the dial apparatus (D) and front view of the 3-D–printed frame in a bilateral system (E). (F) Additional prototyping included experimenting with the positioning of the magnet casing, which influenced lid/spectacle interactions.

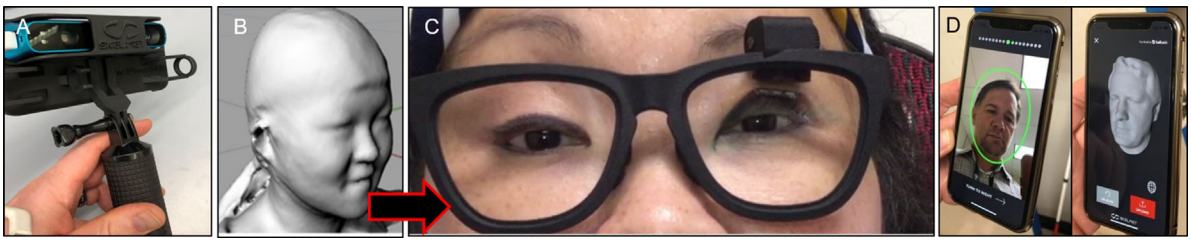

Figure 4. Craniofacial 3-D scanning and printing methods. (A) Structure sensor attachment for iPhone 8. (B) Craniofacial scan produced for participant 5 using (A). (C) Custom MLP frame generated for participant 5 from (B). (D) The sensor attachment is no longer needed for iPhone models X and above.

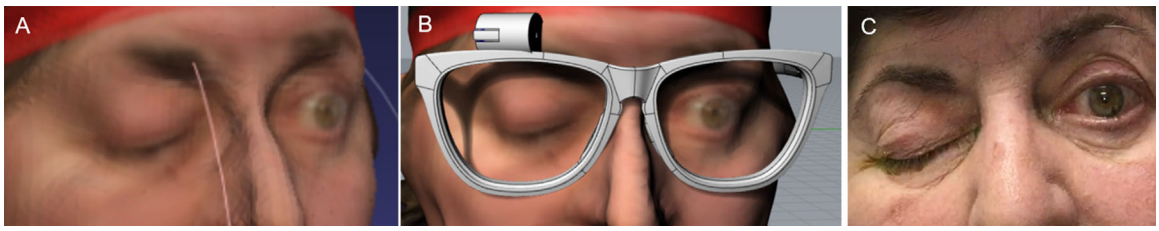

Figure 5. A poor fitting custom frame in one participant prompted review of data quality resulting in identification of a scanning error. It is evident, when comparing the scans in A and B to the ground truth (C), that there was an error in the scan of the nasal bridge, such that it was rendered too narrowly. Abrupt movement by the participant or scanning device was suspected of causing this error.

The sleeve fitted into the cavity of the housing, which was integral to the frame (i.e., not an attachment). This sleeve approach was implemented for the custom MLP, which, unlike the non-custom version had a slot for an optical flathead screwdriver and notches that interlocked with a flexible pin on the casing, creating a lineal dial adjustable in 45° increments. A second iteration allowed adjustment in 30° increments per clinical staff requests. There was one incident of a patient breaking the frame at the magnet casing-frame joint, and multiple instances of the locking pins on the rotatable element cracking off, which may have been in part due to the fragility of the material used in stereolithography 3-D printing.

Cranio-Facial Scanning Results

Cranio-facial scans were done with a stereo camera attachment on an iPhone 8 via an app developed by Skelmet Inc. (Fig. 4A). More than half way through the study period, Skelmet Inc. introduced a new app for iPhone X, which was also tested and did not require the third-party stereo camera attachment. All of the main bony features of the face were measured by the software as well as the pupil and helix of the ear, which were used in custom frame generation. The detailed algorithms used by Skelmet Inc. are proprietary and so are not able to be reported.

Requests by the manufacturer for re-scan were common but became less frequent as the clinicians became more familiar with the process and ways to optimize scan data capture. Acceptable scans (as judged by the manufacturer) were possible for all eight of the participants scanned. Suboptimal custom frame generation occurred three times, in participants 3, 7, and 8. In cases 7 and 8 the frame sat too low, limiting the amount of opening. For participant 3, the frame sat too high, and the lid would not open (force too low). Detailed review of this case (Fig. 5) suggested an error in the scan data, presumably from participant movement. More specifically, the participant's nose was rendered more narrowly than the ground truth (Fig. 5C), causing the frame to sit higher than intended.

Primary Benchmark Results

The primary benchmark for this phase I study was successful fitting in greater than 50% of participants, defined as a patient-clinician satisfaction with fit without adverse events during 20-minute in-office trial, greater than 5 of 10 comfort rating, and desire/approval to do a 20-minute trial. Of the 10 enrolled participants (Table), eight patients returned for fitting with the custom MLP after the scan and prototype production, and 88% (7/8) were successfully fitted in at least one eye. The median improvement in lid opening was 2.3 mm (1.3 to 5.0), which was significant ($P = 0.01$, Wilcoxon). Participant 7 could not be fitted

Figure 6. Study participant photos of eye-open state with no device, standard non-custom MLP, and custom MLP. There is near ideal fitting with non-contact supension of the eyelid in participants 2, 3, 5, and 6. Participants 7 and 8 had low fitting frames, and, although the ptosis was improved in at least one eye, the upper field is limited, and there is contact between the spectacle magnet buffer and the eyelid magnet. Despite contact, participant 9 had a good frame fit height with symmetrical opening. Participant 10 fit was slightly low.

successfully after one attempt and was unable to return for re-fit due to other health concerns, causing difficulty traveling to the research clinic.

All seven participants who were successfully fitted preferred the custom frame over a standard frame. Median participant reported comfort with the best fit version was very good at 9 of 10 (twenty-fifth to seventy-fifth interquartile range, 7–10). Images of participants and blink plots of the participants are in Figures 6 and 7 below. Analysis with exact binomial test suggested, with 80% power, that the true population success rate would be significantly greater than 45% ($P = 0.05$). All six of the patients with initial fitting success also had a successful 20-minute trial, and five

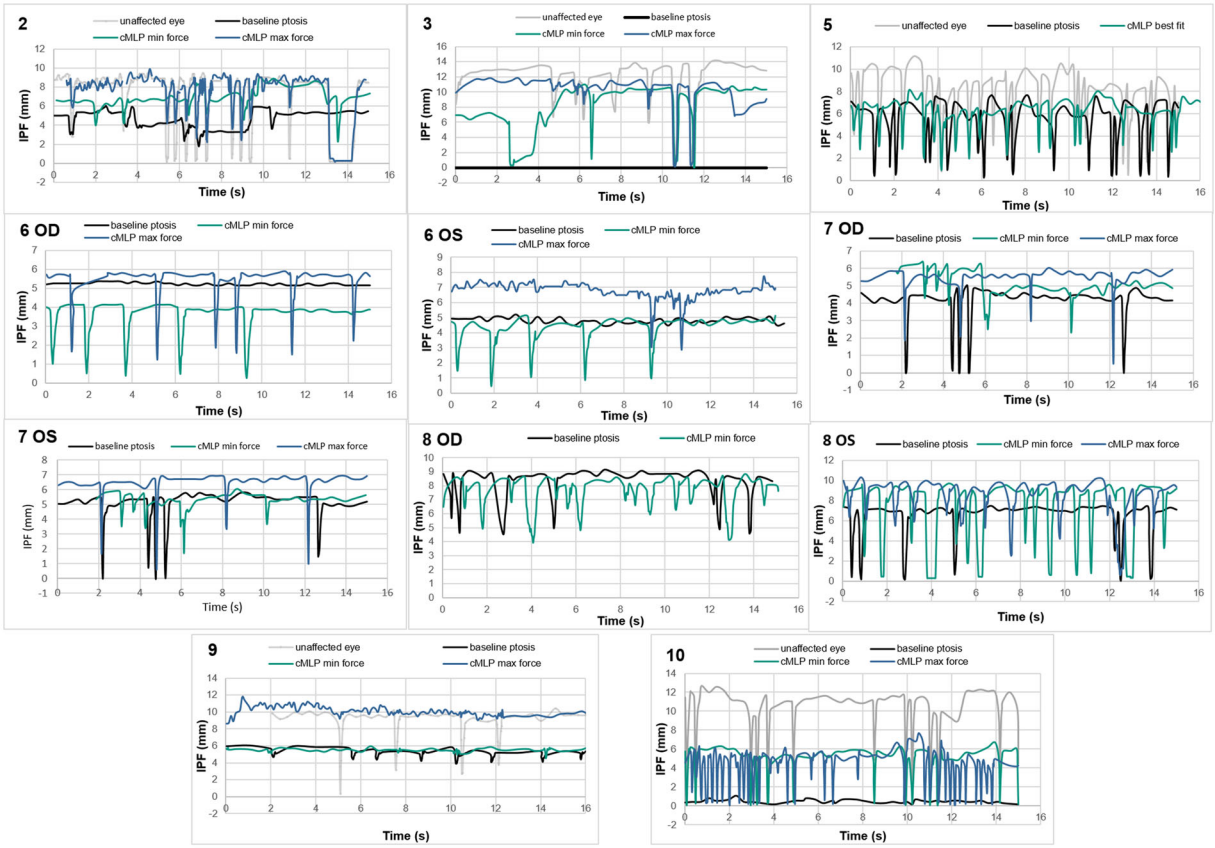

Figure 7. Blink plots showing interpalpebral fissure (IPF) for each participant at baseline and with custom MLP (cMLP) at highest and lowest force settings. The unaffected eye was also plotted for unilateral cases. Participants 5 and 8 did not have max force data because of discomfort (force much too strong). Subject 6 had a worsening of ptosis in the right eye with the MLP on the lowest setting, which may be explained by weight of the magnet array.

took the custom MLP home for a one-week trial. At-home trials were promising, with no adverse events except mild conjunctival redness for participant 2, which resolved without treatment in one day after study completion. The patient who did not take the device home, participant 8, was approved to do so for the left eye but chose to defer until re-printing was done, in the hopes of having an adequate fit for both eyes (the participant had bilateral ptosis due to chronic progressive external ophthalmoplegia). The study period ended before she could be refitted. Long-term use of the device beyond one week was not part of this phase I study. Compared to the prior study where participants of Asian descent were not able to obtain an acceptable non-custom frame fit, both Asian participants in this study were successfully fitted with the custom frame approach and wore the device for the extended one-week trial without complications.

Secondary Benchmark Results

The secondary outcome was a greater than 1 mm lid position change between the highest and lowest force setting in greater than 50% of participants. Ten eyes of seven patients had data for the rotation experiment with 80% (eight of 10) of eyes and six of seven patients (86%) meeting the greater than 1 mm benchmark, which was significant by exact binomial test ($P = 0.05$). This suggested a greater than 45% true population success rate for the adjustable force feature. Changes in lid position via force modulation can be visualized in the blink plots in Figure 7. The median change in fissure height from lowest to highest force setting was 1.5 mm (0.8–2.7; $P = 0.06$).

Discussion

Here we demonstrate the successful implementation of a new custom frame version of the MLP that uses existing commercially available techniques to provide 3-D craniofacial scans using a smartphone app. It also incorporated a built-in adjustable force magnet housing with a lineal dial that allowed adjustment of

the magnetic force and lid position. This is the first report of the angular translation approach for force adjustment feature combined with the custom frame approach.

In this phase I equivalent proof-of-concept study, the aims were (1) to prototype the built-in component system and (2) to test the system with the help of participants with severe blepharoptosis to determine clinical feasibility. The primary hypothesis was that there would be statistically greater than 50% initial fitting success rate with the custom system. Based on our predefined criteria, the initial fitting success rate was 88%. The binomial statistical test used suggests that the success rate in the true clinical population should be at least 45%, very close to the 50% benchmark set by consultation with clinical low-vision rehabilitation optometry specialists. They indicated this would be the minimum success rate that would make clinical implementation feasible and would represent a success rate similar to spectacle mounted low vision aids such as bioptic telescopes. We expect that continued refinement of MLP design and approaches in phase II would further improve the fitting success, before the device would go to market. According to our study, there is a reasonable likelihood that the custom MLP will be at least as acceptable to patients clinically for ptosis as spectacle-mounted telescopic low-vision aids are for patients with low vision.

A second benchmark was a greater than 1 mm change in interpalpebral fissure across the adjustable force range in statistically greater than 50% of participants, which served to determine whether inclusion of this feature was supported. Eighty percent of our sample met this criteria. Based on this proportion, the binomial test would suggest that adjustable force is likely to be useful in at least half of the patients in clinical practice, although it could be higher. Changes in lid position via force modulation can be visualized in the blink plots in Figure 7. The 1.5 mm median change in fissure height measured from lowest to highest force should be enough to be clinically meaningful, and it is recommended that the rotational dial mechanism be included in future studies.

There is only one prior published study on magnetic ptosis correction. In that study, two patients of Asian descent were enrolled but could not be fitted, as compared to two of two being successfully fitted with the custom frame approach in this study. This is a major success, opening the potential for treatment to this cohort of patients, while not excluding potential benefits in fitting success of other non-Asian patients with low bridge anatomy or facial structures outside the normative ranges. Such other examples were evident in our sample including participants 2 and 8, who were of small and petite stature, and participant 9 who was of African descent and also had low bridge anatomy. The approach of custom frame generation may be considered for spectacle-mounted low vision aids as well.

This was a phase I study, and therefore the sample size was small and there was not a comparison group. It was not designed to determine efficacy against a control group or show superiority over a standard frame, merely to determine whether the custom 3-D printed frame approach was feasible. We also note that the follow-up time was only one week. As such, the results should not be interpreted as definitive for safety or efficacy. An ongoing study is comparing a non-custom version of the MLP to eyelid taping procedures and a sham device over longer follow-up times, to address this gap in the literature. Moreover, our results are not meant to support immediate implementation of the approach into clinical practice, because the MLP, in any of its forms, is not available commercially.

Conclusions

The 3-D custom MLP frame approach using a smartphone app-based craniofacial scan appears to be feasible likely to improve the fitting success of the MLP. Further development and study of this approach is warranted.

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References

1. Leatherbarrow B. *Oculoplastic Surgery*, 2nd edition. Boca Raton: CRC Press; 2010.
2. Sridharan GV, Tallis RC, Leatherbarrow B, Forman WM. A community survey of ptosis of the

eyelid and pupil size of elderly people. *Age Ageing*. 1995;24:21–24.
3. Yoon KC, Mun GH, Kim SD, et al. Prevalence of eye diseases in South Korea: data from the Korea National Health and Nutrition Examination Survey 2008-2009. *Korean J Ophthalmol*. 2011;25:421–433.
4. Bacharach J, Wirta DL, Smyth-Medina R, et al. Rapid and sustained eyelid elevation in acquired blepharoptosis with oxymetazoline 0.1%: randomized phase 3 trial results. *Clin Ophthalmol*. 2021;15:2743–2751.
5. Shah-Desai SD, Aslam SA, Pullum K, Beaconsfield M, Rose GE. Scleral contact lens usage in patients with complex blepharoptosis. *Ophthalmic Plast Reconstr Surg*. 2011;27:95–98.
6. Phillis K, Brocks D, Carrasquillo KG. Case report: use of prosthetic replacement of the ocular surface ecosystem treatment of traumatic lid ptosis in a pediatric patient. *Optom Vis Sci*. 2020;97:1029–1033.
7. Cherny C, Sherman SW, Glass LRD. Severe chronic progressive external ophthalmoplegia–associated ptosis successfully treated with scleral lenses. *J Neuroophthalmol*. 2021;41:e189–e191.
8. Lapid O. Eyelid crutches for ptosis: A forgotten solution. *Plast Reconstr Surg*. 2000;106:1213–1214.
9. Goldzieher W. Einfachstes verfahren gegen ptosis und entropium spasticum senile. *Centralblatt f Augenheilkd*. 1890;14:34–36.
10. Meyer A. Treatment of ptosis. *Arch Ophthalmol*. 1893;22:226–230.
11. Findlay M, Heckmann JM, Sivarasu S. Three-dimensional printed patient specific ptosis crutches as a nonsurgical solution for elevating upper eyelids in myasthenia gravis patients. *J Med Devices*. 2016;10.
12. Sun MG, Rojdamrongratana D, Rosenblatt MI, Aakalu VK, Yu CQ. 3D printing for low cost, rapid prototyping of eyelid crutches. *Orbit*. 2019;38:342–346.
13. Houston KE, Pachalis EI, Angueira DC, Bronstad PM, Barrett AM, Iaccarino MA. Restoration of vision after brain injury using magnet glasses. *Am J Phys Med Rehabil*. 2017;96(4):e70.
14. Houston KE, Tomasi M, Yoon M, Batalha G, Paschalis EI. An external magnetic device for severe bilateral blepharoptosis: proof of concept (abstract). *Optom Vis Sci*. 2015;92.
15. Houston KE, Tomasi M, Yoon M, Paschalis EI. A prototype external magnetic eyelid device for blepharoptosis. *Transl Vis Sci Technol*. 2014;3:9.
16. Singh NK, Paschalis EI, Tomasi M, Rizzo JF, Houston KE. The Boston blink-netic project: preliminary outpatient feasibility results (abstract). *Optom Vis Sci*. 2016;93: E-abstract 16118.
17. Houston KE, Tomasi M, Amaral C, et al. The magnetic levator prosthesis for temporary management of severe blepharoptosis: initial safety and efficacy. *Transl Vis Sci Technol*. 2018;7:7.
18. Houston KE, Paschalis EI, Tomasi M. Active magnetic prosthesis for eye-lid re-animation 36770-559P01US. United States patent application US 16/607, 143. 2020 Dec 10.